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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,572

05/25/2006

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0508-1155

1034

466

7590

05/01/2008

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

05/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

The previous restriction requirement has been withdrawn in favor of the instant restriction requirement stated below.

#### ***Election/Restriction***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- |             |   |
|-------------|---|
| Invention 1 | Claim(s) 20-29 and 36, drawn to an enzymatically-active glutamine:fructose-6-phosphate amidotransferase and composition.  |
| Invention 2 | Claim(s) 30-32, drawn to a nucleic acid, recombinant vector and vector.   |
| Invention 3 | Claim(s) 33-35, drawn to a purification process for a protein from a solution comprising brining said solution into the presence of a compound binding specifically tot the purification tag of said protein. |
| Invention 4 | Claim(s) 37, drawn to a method for screening of compounds modifying the activity of a protein.  |
| Invention 5 | Claim(s) 38, drawn to a method for screening of compounds useful for treatment or prevention of diabetes, in particular type II diabetes, obesity, acidosis, ketosis, arthritis, cancer, or osteoporosis.     |

The inventions listed as Inventions 1-5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among Inventions 1-5 is an enzymatically-active protein comprising a GFAT (glutamine:fructose-6-phosphate amidotransferase) sequence and at least one purification tag sequence being inserted between two consecutive amino acids of the GFAT sequence. However, the combination of the references of Chang et al. (J Biol Chem. 2000 Jul 21;275(29):21981-7; PTO 892) and Ferguson et al. (Protein Sci. 1998 Jul;7(7):1636-8; PTO 892) teach such enzymatically-active protein.

Chang et al. teaches the human glutamine:fructose-6-phosphate amidotransferase fused to glutathione S-transferase, which was found to have low specific activity (see entire publication especially pages 21982-21986). Ferguson et al. teach FhuA having an internal hexahistidine purification tag inserted after amino acid 405 which resides in a known surface-exposed loop.

Therefore, it would have been obvious to one of ordinary skill in the art to insert the internal hexahistidine purification tag taught by Ferguson et al. between two amino acids located on surface-exposed loops on the glutamine:fructose-6-phosphate amidotransferase (GFAT) taught by Chang et al. One of ordinary skill in the art would have been motivated to do this for the purposes facilitating purification of the human GFAT taught by Chang et al. with greater specific activity compared to the GFAT fused to glutathione S-transferase.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the inventions lack the same or corresponding special technical feature, then the inventions listed as 1-5 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: SEQ ID NOs: 1-12.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

A same or corresponding technical feature shared among the species is an enzymatically-active protein comprising a GFAT (glutamine:fructose-6-phosphate amidotransferase) sequence and at least one purification tag sequence being inserted between two consecutive amino acids of the GFAT sequence. However, the combination of the references as stated above of Chang et al. (J Biol Chem. 2000 Jul 21;275(29):21981-7; PTO 892) and Ferguson et al. (Protein Sci. 1998 Jul;7(7):1636-8; PTO 892) teach such enzymatically-active protein.

Thus, the same or corresponding technical feature is not special since it was known in the prior art and therefore cannot make a contribution over the prior art. Since the species lack the same or corresponding special technical feature, then the species listed SEQ ID NOs: 1-12 are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the**

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**patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929.

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The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Patent Examiner

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